DEPARTMENT OF HEALTH AND HUMAN SERVICES

95170d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 12, 2005

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 05-12

Chris Dawn, President
Greenland, Inc.
815 South Weller Street
Seattle, Washington 98104

WARNING LETTER

Dear Mr. Dawn:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your advertisement for your product, "Naturin2", that appeared in the monthly magazine "Preserving Health Life", published by the *World Daily Journal* on October 13, 2004. Our review of this advertisement has determined that the product "Naturin2" is promoted for conditions that cause the product to be a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)(1)(B)]. The therapeutic claims in this advertisement establish that this product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of such claims made in your advertisement include:

- "Fighting Disease.... [E]nhancing body resistance to bacteria and virus, ...treating systemic lupus erythematosus (SLE)...."
- "Anti-Cancer and Prevent Cancer: Inhibiting cancer cell growth, preventing cancer cell spreading, significantly reducing toxic effects from radiation and chemotherapy."

Your product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended purposes. Thus, your product is misbranded under section 502(f)(l) of the Act [21 USC 352(f)(1)] in that the labeling for this drug fails to bear adequate directions for

use. It is a violation of section 301(a) of the Act [21 USC 331(a)] to introduce or deliver for introduction into interstate commerce any drug that is misbranded.

Even if your product's intended use did not cause it to be a drug, the product would violate the Act and FDA regulations because it does not comply with the following food labeling requirements:

- Because the product is a beverage, the declared serving size must be based on the Reference Amount Customarily Consumed (RACC) for beverages [21 CFR 101.9(b)(2) and 101.12]. Your product's serving size declared on the 16 ounce multi-serving product label is 40 milliliters (ml), whereas the RACC for beverages is 240 ml [21 CFR 101.12].

- Your product's nutrition information ("Nutrition Facts"), ingredient statement, and manufacturer's name and address that appear on the information panel must appear together without intervening material [21 CFR 101.2(b) & (e)].

This letter is not intended to be an all-inclusive review of your firm's products and their labeling. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement actions without further notice. Possible enforcement actions include seizure and obtaining a court injunction against further marketing of your products.

Please respond in writing within (15) fifteen days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state the time at which corrections will be completed. Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Charles M. Breen
District Director

cc: WSDA with disclosure statement